The correct procedure for Defendant Keystone to follow should have been the following: when a new patient called Defendant Keystone to schedule a hearing test, Cheryl Henson, the secretary, should have asked them if they have seen their family doctor about their hearing problem. If they had not, she could have told them either that their FIP may not cover the test because they were not referred from their doctor or that they should contact their doctor, and get a referral for testing.

Defendant Keystone scheduled patients whether they had a referral or not because Defendant Fowler did not want the patient to be persuaded by their family physician to go elsewhere. Defendant Fowler was aware that the primary physicians may have had a different audiologist (other than Keystone) that they might want to refer their patients to. Also, a lot of primary physicians will refer patients to an ENT (ear, nose, and throat) doctor, instead of an audiologist, since the ENT doctor will rule out any options for surgery etc. that can improve some types of hearing loss. Some ENT practices also have an audiologist or hearing instrument specialist who works for them, so they may review hearing aids with the patients, and then the patient might purchase hearing aids from them and never go to Defendant Keystone's facility. If any of the above happened, Defendant Keystone would lose that patient and money.

After Defendants Fowler and/or Price treated a patient, Defendant Keystone would start the billing process by entering services into 'Sycle.net' which would then populate over to the claim form. This form includes several fields including "*Rendering Provider*" which is the audiologist and "*Referring Provider*" which is the family physician who referred the patient.

When audiologist Defendants Fowler or Price were scheduled to see a patient, and that patient was not referred by a primary physician, the field "Referred By" would often be left blank, or the word "Other " would be chosen to be entered into this field.

Defendant Keystone would instruct its secretary, Cheryl Henson, to research and then enter the patient's primary care physician and his/her NPI # number as the referring provider into Sycle.net; even though this primary physician had not referred this patient.

Relator treated Patient DRA on March 5, 2008. Cheryl Henson, Defendant Keystone's secretary, completed the top potion of the form. The "Referred by" line is blank because this patient was not referred by their family doctor. There was no referral listed in the patient's chart.

On July 13, 2011, Defendant Fowler saw patient MHA and billed CPT 92557 comprehensive audiological evaluation at $97.00 and was paid $31.79, and CPT 92550 tympanogram / reflux and billed $70.00 and was paid $16.32. Relator noted

that Sycle.net's appointment note states under referral as "other" and that patient purchased her hearing elsewhere and needed it fixed.

On August 28, 2011, Defendant Fowler saw patient CMB without the required referral for CPT 92557 comprehensive audiological exam, billed at $97.00 and paid $35.20, and CPT 99213 (code not allowed to be billed by an audiologist) an office visit which wasn't completed for $65.00. Relator checked patient's chart and noticed that there was no referral.

On June 25, 2013, Relator saw patient TB for only a hearing aid assessment (V5010) which does not require a referral. However, Defendant Keystone actually billed FIP for CPT 92557 a comprehensive audiological test at $97.00 with payment of $36.16; this required a referral. Although the patient called his doctor for a recommendation, neither Defendant Keystone nor its staff ever obtained the required official referral to Defendant Keystone's facility.

On May 29, 2014, Defendant Fowler saw patient DWA for a comprehensive hearing evaluation. On the patient's appointment summary in Sycle, it is noted that this patient was referred by "Other" and it listed the patient's wife, who was not a physician. Defendant Keystone billed FIP under code CPT 92557 for $97.00 and was reimbursed $28.86.

Defendant Keystone regularly presented fraudulent claims to FIP for services rendered by Defendants Fowler and/or Price and/or Relator. These claims were

fraudulent because these patients were not referred, as required, for diagnostic testing. But for the fraudulent listing of the family doctor's NPI #, Medicare and other FIP would not have reimbursed Defendant Keystone for the services.

Defendant Keystone has falsified referral authorization requests in order to obtain reimbursement. In some instances, Defendant Keystone has induced office staff, including but not limited to Relator, to request a referral from the family doctor *after* the patient was seen. This was done so that it would appear as if Defendant Keystone had a legitimate referral *before* it saw a patient. Defendant Fowler would often see a patient; bill the FIP and later direct Relator or the secretary to call the primary physician and ask the doctor to backdate the referral; days, weeks or months after the patient was treated. Several doctors agreed to fraudulently backdate the referral in violation of FIP rules. On other occasions, Defendant Keystone would change the date of service to a later date to be in compliance with the date of referral.

On several occasions Relator discussed with Defendant Fowler her reservation about submitting claims that were not actually referred by the patient's primary physician in order to obtain FIP reimbursements; he responded by entering the referral information himself into the electronic billing system as well as submitting the claims for patients either he or Defendant Price treated.

Defendant Keystone, has, on the referral requests, fabricated the reasons to the patient's family doctor as to why that patient required Defendant Keystone's particular services. In doing so, Defendant Keystone has not only made false statements material to false or fraudulent claims, making it liable under the False Claims Act, but it has also wantonly disregarded patient privacy protections under HIPAA.

Defendant Fowler would perform all or part of a tympanograms/reflex test, CPT code 92550, but he would not always print out the patient's results. Instead he would instead hand-draw a 'tymp' in the chart (normal tymps when printed out look like an upside-down "V"). There were also times when Defendant Keystone billed for these tests when they were not medically necessary. Defendant Fowler sometimes conducted these tests, *without always getting a referral and without marking in the patient's chart why the test was medically necessary*, because he knew Defendant Keystone would receive reimbursement, depending on the patient's FIP.

HIPAA introduced two additional bases for criminal liability that expressly prohibit the kind of "scheme," "trick," and "artifice" entailed by Defendant Keystone's falsification of prior referral and/or authorizations:

> Under the title "*False statements relating to health care matters*," 18 U.S.C. § 1035(a) provides penalties including up to five years of prison for a person who "in any matter involving a health benefit program, knowingly and willfully – (1) falsifies, conceals or covers up by trick, scheme or device a

> material fact; or (2) makes any materially false, fictitious, or fraudulent statement or representation, or makes any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry." Similarly, under the title "*Health Care Fraud*," 18 U.S.C. § 1347 provides for penalties including up to ten years of prison for any person who "knowingly and willfully executes, or attempts to execute, a scheme or artifice – (1) to defraud any health care benefit program; or (2) to obtain by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by ...Claims billed to insurance with primary care physician used as referring physician on the claim, when they were not referred for diagnostic testing.

Many claims Defendant Keystone submitted to FIP for diagnostic testing, were actually for tests that were routine in nature, conducted during regularly scheduled follow-up appointments, when the patient wanted to pursue new hearing aids, and/or for other hearing aid related issues. No referral was obtained for these diagnostic tests; a requirement pursuant to Audiology Guidelines, as well as Medicare Guidelines. Testing always needs to be medically necessary and a referral must be obtained prior to conducting diagnostic tests. The reason for performing the test should always be documented in the patient record, but it was often not known why the Defendant Keystone patients were first seen when referring to their charts for information.

Tests can be completed without a referral. You would just have to let the patient know that they will be financially responsible for the cost of the test. Relator has information on hundreds of patients that were treated at Defendant Keystone without a referral yet still billed to FIP.

Upon information and belief, Defendant Price also failed to secure referrals before testing her patients and knew or should have known some of her services were not medically necessary.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants'

fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

c. FAILED TO HAVE COMPLETE PATIENT CHART / RECORDS

28 Pa Code § 25.214 provides the following:

> A registrant shall, upon the consummation of a sale of a hearing aid, keep and maintain records in the registrant's office or place of business at all times. These records shall be kept for 7 years and shall include the following: (1) Results of all testing conducted under § 25.209 (relating to facilities, procedures and instrumentation). The minimum acceptable test records shall be records of: (i) Pure tone tests including air and bone conduction with masking where appropriate, and the ambient noise level of the test area. (ii) Speech reception threshold expressed in decibels of hearing level. (iii) Most comfortable level expressed in decibels. (iv) Uncomfortable (tolerance) level expressed in decibels. (v) Word discrimination test results expressed in percentage indicating the test words used, presentation level, masking level (if applicable), and signal to noise ratio (if applicable). (2) A copy of the written receipt, disclosure agreement and money back guarantee required by § 25.210 (relating to receipt, disclosure agreement and money back guarantee to purchaser—purchaser protection). (3) The written physician's recommendation required by § 25.212 (relating to medical recommendations by examining physicians) or the waiver form required by § 25.211 (relating to medical recommendations; waiver forms).

Medicare requires that all audiological diagnostic tests be documented with sufficient information so that Medicare contractors may determine that the services do qualify as an audiological diagnostic test. *Center for Medicare Service* Related Change Request # 6447, p. 6 (2010).

The interpretation and report shall be written in the medical record by the audiologist, physician or non-physician practitioner who personally furnished any audiology service or by the physician who supervised the services. Technicians shall not interpret audiology services, but may record objective test results of services that may furnish under physician supervision. Payment for the interpretation and report of the services is included in payment for all audiology services. *Center for Medicare Service* Related Change Request # 6447, p. 6 (2010).

49 Pa. Code § 45.101 provides:

> (a) A licensee shall maintain a record for each person served which accurately, legibly and completely reflects the evaluation or treatment of that person. A record shall be prepared and retained irrespective of whether treatment is actually rendered or whether a fee is charged. The record shall include, at a minimum: (1) The name and address of the person served and, if that person is a minor, the name of the parent or guardian. (2) The date of each visit by the person served. (3) A description of the complaint, symptoms and diagnosis of the person served. (4) A description of the treatment or service rendered at each visit and the identity of the licensee or assistant rendering it. (5) The date of each entry into the record bearing on evaluation or treatment and the signature of the licensee. (b) A licensee shall retain records for a person served for a minimum of 7 years from the date of the last entry. A licensee shall retain and store the records in a safe location to maintain confidentiality. (c) A licensee shall comply with a written, dated and signed transfer of records request from a person served, or from that person's parent or guardian if the person is a minor within a reasonable period of time upon receipt of the request. A legible copy of the record shall be provided either gratuitously or at a charge which reflects the licensee's cost of duplicating and forwarding the record. (d) A licensee's failure to comply with this section will be considered unprofessional conduct under § 45.103 (relating to unprofessional conduct) and will subject the noncomplying licensee to disciplinary action under section 5(4) of the act (63 P. S. § 1705(4)). (e) This section does not apply to licensees acting within

the scope of their employment under section 6(b)(2) of the act (63 P. S. § 1706(b)(2)).

49 Pa. Code § 45.102 (d) *Principles of Ethics II.* (1) A licensee shall hold paramount the welfare of persons served professionally. (iv) A licensee shall provide appropriate access to the records of a person served professionally.

49 Pa. Code § 45.102(e) *Principle of Ethics III.* (1) A licensee shall maintain high standards of professional competence. (iv) A licensee shall maintain adequate records of professional services rendered.

49 Pa. Code § 45.103 provides that as used in section 10(5) of the act (63 P. S. § 1710(5)), the term ''unprofessional conduct'' includes, but is not limited to, the following types of conduct: (17) Failing to comply with § 45.101 (relating to preparing, maintaining and retaining records).

There were several times when Relator would be treating a patient and looked at their chart and either noticed that there were no documents, incomplete documents or incomplete treatment dates for this patient; that Defendant Fowler would not include any history of why the patient is present nor any information on if the patient was referred for this test; he would not include his clinical assessment or a recommendation; he would not include procedures executed and the diagnostic test results for each procedure; and that he would sometimes simply use that

patient's previous hearing test and just mark over it any changes instead of doing all parts of the test and placing the results on a new form.

When Medicare reimburses a provider for a service, that reimbursement includes the provider sending a patient's referring physician a copy of its medical interpretation notes and records.

Although Defendant Keystone was reimbursed for its service it rarely provided the referring provider with its medical treatment records in part because there were no such complete records to send.

Defendant Fowler would often give Relator sticky notes with information on the patient's treatment so that she could enter into Sycle.net instead of providing her with complete medical records.

On August 28, 2011, Defendant Fowler allegedly saw patient CMB and billed for CPT 99213 (code audiologists are not allowed to bill) for an office visit. Defendant Fowler failed to put documentation in this patients chart detailing that he completed a comprehensive patient history; said documentation is required by FIP.

On May 30, 2013, Defendant Fowler saw patient RAB for CPT 99212 (code audiologists are not allowed to use) for an office visit that he did not complete that he billed FIP $55.00 paid .94 with a patient co-pay of $40.00. There was none of the required documentation in the patient's chart to make it eligible to be billed.

On June 25, 2013, Relator saw patient TB. Defendant Keystone billed FIP for CPT 92557 a comprehensive audiological test at $97.00 with payment of $36.16, and CPT 99201 office visit (a code not allowed to be billed by an audiologist and not allowed to be conducted by Relator) at $65.00 and paid $11.78, plus Defendant Keystone also billed the patient TB, a $30.00 copay for that service that wasn't done. There was not documentation in the patient's charts that the above was completed.

On July 30, 2013, Defendant Fowler treated patient DRA and billed the FIP for $152.00. This charge is broken down as $55.00 for office visit under CPT code 99211 and $97.00 for a comprehensive audiological exam CPT 92557. This patient did not have the required comprehensive history notes in her chart to allow for billing of an "office visit" nor did this patient have the required notes in her chart to document that the comprehensive audiological exam was completed. Defendant Keystone's failure to have the required notes in this patient's file made it ineligible to bill the Federal Insurance Program for these services. However Defendant Keystone billed the Insurance Program for $152.00 for both services and received payment of $62.94.

On May 29, 2014, Defendant Fowler saw patient DWA. The documentation in the chart shows that Defendant Keystone billed FIP for an office visit under CPT 99201 (a code an audiologist is not allowed to bill under) for $65.00. Medicare

denied payment based on this code. Defendant Keystone forwarded this bill to Highmark Blue Shield. Patient's chart fails to have documentation which shows a comprehensive history of the patient was taken. This lack of documentation should not have allowed Defendant Keystone to bill for an office visit.

On May 19, 2010, Defendant Fowler saw patient EFA and billed FIP for $65.00, CPT 92506 (a code not allowed to be billed by an audiologist) as an evaluation of speech, language, voice or communication; lack of documentation in this patient's chart probably shows that Defendant Fowler did not conduct this exam which makes Defendant Keystone ineligible to bill the FIP for this service.

Defendant Fowler would sometimes write Defendant Price's medical notes / report for her. Defendant Price also failed to have complete charts, notes and supporting documents on some of her patients to support the claims billed to FIP.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for

reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

i. Failed To Receive A Disclosure Agreement

Pennsylvania statute requires that each hearing aid customer must receive a disclosure agreement and a money back guarantee which is required by Act 153. The provider must also be required to retain copies of those documents in their records.

28 Pa. Code§ 25.210 Receipt, disclosure agreement and money back guarantee to purchaser—purchaser protection provides:

(a) Receipt. Upon the sale of a hearing aid, the registrant shall provide the purchaser a signed receipt. The receipt may be made out on more than one sheet

of paper and shall contain the following: (1) The date of sale. (2) The make, model and serial number or, if no serial number is applicable, an identification number of the hearing aid. (3) The address of the principal place of business of the registrant. (4) If the hearing aid is used or reconditioned, a statement which provides that information and which meets the requirements of § 25.215(23) (relating to denial, revocation or suspension of registrant's certificate). (5) The registrant's registration certificate number. (6) The terms of any guarantee or express warranty made to the purchaser with respect to the hearing aid. (7) A copy of the written forms as required by § 25.211 (relating to medical recommendations; waiver forms). (8) A statement on or attached to the receipt, in no smaller than 10 point type, as follows: ''The purchaser has been advised at the outset of his relationship with the hearing aid dealer that any examination or representation made by a registered hearing aid dealer and fitter in connection with the practice of fitting and selling of this hearing aid, is not an examination, diagnosis or prescription by a person licensed to practice medicine in this Commonwealth and therefore must not be regarded as medical opinion.'' (9) A statement on the face of the receipt, in no smaller than 10 point bold type, as follows: ''If your rights are violated, you may contact the State Bureau of Consumer Protection, the Pennsylvania Department of Health in Harrisburg, or your local district attorney.'' (b) Disclosure agreement and money back written guarantee. Before the provision of any service incidental to or connected with the potential sale of a hearing aid, the registrant shall provide a disclosure agreement and money back written guarantee to the prospective hearing aid user or authorized representative, and shall explain it in detail in accordance with subsection (c). This shall be in 10 point type or larger, and may be made out on more than one sheet of paper, but shall employ the following format or be on a form approved by the Department:

29 Pa. Code § 25.213 *Consumer Review* provides:

(a) Before signing a waiver form under § 25.211 (relating to medical recommendations; waiver forms) and before the sale of a hearing aid to or for the use of a prospective hearing aid user, the registrant shall: (1) Provide the prospective hearing aid user or authorized representative with a copy of the User Instructional Brochure for the hearing aid that has been or may be selected for the prospective user. (2) Review the content of the User Instructional Brochure with the prospective hearing aid user or authorized representative orally or in the predominant method of communication used during the sale. (3) Give the prospective hearing aid user or authorized representative an opportunity to read the User Instructional Brochure. (b) If goods or services having a sale price of

> $25 or more are sold or contracted to be sold to a purchaser as a result of or in connection with a contact with or call on the purchaser at the purchaser's residence, the purchaser may avoid the contract or sale by notifying the registrant of that decision, in writing, within 3 full business days following the day on which the contract or sale was made and by returning or holding available for return to the registrant, in its original condition, any merchandise received under the contract or sale. The notice of rescission is effective when deposited in the United States mail or when service is made in another manner which gives the registrant notice of rescission. These and additional provisions relating to the sale of goods in the purchaser's home, including specific items which shall be included on the purchase receipt, are made a part of this section by incorporation of section 7 of the Unfair Trade Practices and Consumer Protection Law (73 P. S. § 201-7).

Hearing Aid Disclosure Forms were often not signed in Defendant Keystone's patients' charts; a requirement pursuant to the Department of Health, Hearing Aid Program, for all professionals who dispense hearing aids. Copies of the Disclosure are also to be given to the patient, which was not done, simply because the Disclosure was not signed in the first place. There were many of Defendant Fowler's patient charts, where the Disclosure Form was missing or left blank. There were also occasions where Defendant Fowler would mail the Disclosure Form, with a copy, to the patient, requesting they sign it and mail it back in the prepaid envelope which was *after* the patient had received service.

Defendant Fowler would often not have a patient sign a disclosure agreement including but not limited to the following patients: CFB - 04/07/11; RMB - 08/22/13; EGF - 05/04/12 or 05/18/12 (sale date and fit date); CWH - 09/08/11; BJL - 05/18/12; and WHM - 05/24/12 (disclosure not signed, but date that clearance

was received (06/12/12), is entered on the disclosure, which was after his actual fitting date).

Upon information and belief, Defendant Price also failed to have her patients sign a Disclosure Agreement and knew or should have known that Defendant Keystone was billing the FIP as if she had done so.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible

payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

ii. Failed To Secure Medical Waiver Signatures

The medical waiver is a form required by the Department of Health to be signed by the patient prior to the sale of hearing aids, if the patient has not been seen by a primary physician or ENT doctor, prior to buy the hearing aids. This waiver provides that "it would be in your best interest to see your physician or an ENT doctor prior to wearing hearing aids, to be sure there isn't any medical reason that you shouldn't wear hearing aids." 28 Pa. Code § 25.211. *Medical recommendations*; waiver forms provides the following:

> (a) Except when selling a replacement of a worn out or damaged hearing aid, when selling a hearing aid for the use of a prospective hearing aid user who is 19 years of age or older, a registrant shall either obtain for the prospective user a medical recommendation that complies with § 25.212 (relating to medical recommendations by examining physicians), or ensure that the prospective user or authorized representative signs a waiver form as provided under section 403 of the act (35 P. S. § 6700-403). The waiver form shall be prepared and used as follows: (1) The waiver form shall be in 10 point type or larger. (2) The waiver shall be read to the prospective hearing aid user or authorized representative and explained in a manners that the individual is not encouraged to waive a medical examination and so that the individual will be thoroughly aware that signing the waiver will not be in the prospective hearing aid user's best interest. (3) The waiver form shall read as follows:

I have been advised that my best interests would be served if I had a medical examination by an otologist or otolaryngologist or any licensed physician before my purchase of a hearing aid. (Registrant's Name) has fully and clearly informed me of the value of such medical examination. After such explanation, I voluntarily sign this waiver. I choose not to seek a medical examination before the purchase of the hearing aid.

Defendant Keystone would place a Waiver Form on the bottom of its Disclosure Statement. Defendant Keystone by and through Defendants Fowler and Price rarely had patients sign said Waiver and/or the Medical Clearance was not obtained, including but not limited to the following: CFB- 04/07/11, date on clearance : 04/12/11; ACG - 05/20/14, date on clearance: 06/06/14; CWH - 09/01/11, date on clearance : 10/03/11; WHM - 05/29/12, date on clearance: 06/12/12; and NLT - 05/27/14, date on clearance: 06/30/14.

Upon information and belief, Defendant Price also failed to get patients to sign medical waivers and knew or should have known that it was required.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the

submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

5. <u>Services Performed By An Unqualified Employee</u>

28 Pa Code § 25.216 (6) provides that an provider may not employee a person to perform a function within the scope of the practice of hearing aid fitter who is not authorized by law to perform the function. The individuals who furnish audiology services in all settings must be qualified to furnish those services. The qualifications of the individual performing the services must be consistent with the

number, type, and complexity of the tests, the abilities of the individual and the patients' ability to interact to produce valid and reliable results. The Audiologist who supervises and bills for the service is responsible for assuring the qualification of the technician, if applicable and appropriate for the test.

FIP will not pay for an audiological test under its guidelines if the test was performed by a technician, even if under the direct supervision of a physician, if the test requires professional skills.

49 Pa. Code §45.102 (e)(2) *Ethical Proscriptions* are as follows:

> (i) A licensee may not provide services or supervision which the licensee is not qualified to perform under the act, nor may the licensee permit services to be provided by a staff person who is not qualified pursuant to the requirements of the act. (ii) A licensee may not delegate to an unlicensed person any service requiring the professional competence of a licensed individual. (iii) A licensee may not offer clinical services by assistants, students or trainees for whom he does not provide appropriate supervision and assume full responsibility. (iv) A licensee may not require or suggest that anyone under his supervision engage in a practice that is a violation of this Code of Ethics.

49 Pa. Code § 45.103 provides the following: As used in section 10(5) of the act (63 P.S. § 1710(5)), the term ''unprofessional conduct'' includes, but is not limited to, the following types of conduct: (4) Delegating to a person duties that the … audiologist … knows, or has reason to know, the person is not competent or authorized to perform.

a. RELATOR INSTRUCTED TO CONDUCT EXAMS

The only test that Relator was legally allowed to perform for Defendant Keystone to be eligible for FIP reimbursement is an Assessment for Hearing Aid (V5010). Defendant Fowler knew that Relator was not qualified to perform CDL tests (Commercial Driver's License for truck drivers) or OSHA tests yet he would allow these tests to be scheduled as "hearing tests" on Relator's schedule. The paperwork for these tests clearly stated that the testing needed to be completed by an audiologist.

Defendant Keystone by and through Defendant Fowler often instructed Relator to see patients in its locations and perform tests on them unsupervised; said tests of which she was not legally licensed or qualified to be able to do.

Although a Hearing Aid Assessment performed by Relator would have been eligible for reimbursement, Defendant Keystone never credentialed Relator with the FIP as a provider.

Defendant Keystone, by and through direction by Defendant Fowler submitted claims, under Defendant Fowler's NPI # number, for reimbursement to FIP for eligible and ineligible services Relator performed. Defendant Keystone, by and through Defendant Fowler, knew these services were ineligible for reimbursement and/or that it was not able to bill for her services under Defendant Fowler's NPI #.

On July 9, 2012, Patient WA was seen by Relator unsupervised. Defendant Keystone billed for the below services and or products under Defendant Fowler's NPI # number because Defendant Keystone failed to register Relator with the FIPs. Defendant Keystone billed FIP the quoted bundled price of $4,200.00 and was paid $1000.00 for a hearing aid services V5257 LT-RT, then it unbundled the price and also billed for CPT 92595 electroacoustic evaluation for hearing aid for $60.00, CPT 92626 for evaluation of auditory rehabilitation status at $65.00 was paid $40.00, V5160 dispensing fee $450.00, and CPT 92593 hearing aid check for $40.00. On June 29, 2012 billed V5010 assessment for hearing aid at $90.00, and CPT 92591 hearing aid examination and selection at $90.00.

On June 25, 2013, Relator saw patient TB for only a hearing aid assessment (V5010) however Defendant Keystone billed FIP for CPT 92557 a comprehensive audiological test at $97.00 with payment of $36.16, CPT 99201 office visit (a code not allowed to be billed by an audiologist and wasn't conducted by Relator) at $65.00 and paid $11.78, plus Defendant Keystone also billed the patient TB a $30.00 copay for that service that wasn't done. Defendant Keystone also billed V5261 a binaural BTE hearing aids at $4,200.00 and was paid $1,000.00. Defendant Keystone billed all the above services / products under Defendant Fowler's NPI number because Relator was not a registered / credential provider.

Defendants Keystone and Fowler did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

b. SECRETARY HENSON WAS INELIGIBLE TO TREAT PATIENTS

Cheryl Henson, Defendant Keystone's secretary in the Hanover office, often provided services for patients that were often charged to the patient when completed. The PA Hearing Aid Regulations state that these services cannot be provided by non-qualified individuals. A person has to be a licensed fitter or an apprentice fitter to work with hearing aids. These services are normally documented in the patient chart notes, in Ms. Henson's handwriting, but not usually initialed or signed. This occurred frequently in the Hanover office when "walk-in" patients presented with a problem. Ms. Henson would provide services such as cleaning the aids, replacing the ear-mold tubing, replacing slim tubes and tips, replacing receivers, replacing mic covers/filters, and used the suction machine to remove wax that was occluded in the hearing aids.

The services listed above that Ms. Henson provided when the patient had initially bought the hearing aid were sometimes paid by a FIP under Defendant Fowler's NPI #. Defendant Keystone knew that in order to receive reimbursement that only licensed staff could perform those services. Patients who were provided services by Ms. Henson include, but not limited to the following: JPB- tube change; FJD- 10/04/12 receiver changed, 01/29/14 cleaned aid and new retention wire; CFB- 09/21/10 changed tip, 11/30/10 changed tube and tip; WHM- 09/07/10 re-glued tube to mold; and MLT- 06/11/14 tube change.

Defendants Keystone and Fowler did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, said Defendants also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

6. Billing For Services That Were Performed By Employees Who Were Never Credentialed For Participation In The FIP

Defendant Keystone employed two audiologists; himself and Defendant Price, as well as a licensed hearing aid fitter; Relator. Each could have been eligible to bill FIP for services they provided; however, only Defendant Fowler was a registered FIP provider.

Defendant Price and Relator should have enrolled in Medicare as a group member because they provided healthcare only as the employee of Defendant Keystone. As a group member they would have reassigned all their benefits to Defendant Keystone; however Defendant never registered Defendant Keystone as a group.

From 2011, through in or around September of 2014, although Defendant Price had her own NPI # number, she had not enrolled as a Medicare or as any other FIP provider, under Defendant Keystone, despite Medical Regulations stating that audiologists must be enrolled and use their NPI # on claims for services they render in an office setting on or after October 1, 2008. *Centers for Medicare & Medicaid Services, Medicare Claims Processing Manual, Pub. 100-04*, at ch. 12 sections 30-3 (A)(2).

Between on or around July 1, 2014 through on or around August 1, 2014, Defendant Fowler went on a month long vacation, during that time all patients were

seen by Defendant Price or Relator. Relator would then be required and directed, by Defendant Fowler, to bill the FIP for these patients' treatment under Defendant Fowler's NPI # number.

In or around September of 2014, Defendant Fowler told Relator to stop billing FIP for any of Defendant Price's patients until Defendant Keystone registers her as a FIP provider.

49 Pa. Code § 45.203 provides the following:

> (a) A business entity may provide services which require licensure, if the following conditions are met: (3) The business entity provides the Board with a list of the licensees employed by the entity. The list shall be updated upon changes in licensed personnel. (b) A licensee may practice as an employee of a business entity which has met the conditions in subsection (a). The Board will not issue nor renew the license of an individual engaging in the practice of a licensed activity through a business entity which does not have a certification on file.

It is not known if Defendant Keystone by and through Defendant Fowler provided any FIP or any Government Agency with the name of its employee, Defendant Price, who was a licensed audiologist. This would make it appear to the FIP as if Defendant Fowler was the only audiologist in the Defendant Keystone's practice.

It is not known if Defendant Price registered under her medical license as working for Defendant Keystone. (Defendant Price failed to register with Medicare and most other FIP)

Defendant Keystone by and through Defendants Fowler and Price knew that Defendant Price was not a federal insurance credentialed provider yet they allowed Defendant Price to treat patients and bill the FIP under Defendant Fowler's NPI # number.

Defendant Fowler would require Relator to change Defendant Price's NPI # to Defendant Fowler's NPI # when billing the FIP for Defendant Price's services. When Relator questioned Defendant Fowler about billing services rendered by Defendant Price under his NPI # number, Defendant Fowler began entering his NPI# himself as well as submitting claims in through the electronic billing system.

Defendant Keystone submitted claims to the FIP for patients using the wrong NPI # entered in the "rendering provider" field on the claim. All claims that were billed to FIP from Defendant Keystone had Defendant Fowler's NPI # as the rendering provider, no matter who saw the patient. When claims were created in Sycle.net, the rendering provider could be changed prior to submitting the claim, which is how it was implemented to be done, pursuant Defendant Fowler.

Patients seen by *Relator* which were billed by Defendant Keystone under Defendant Fowler's NPI # number include but are not limited to the following: RCBL- 05/27/10; DLP - 07/07/10; SAP- 07/15/10; JAH - 07/21/10; AJM - 01/14/11; FBR - 02/09/11; MJL - 03/02/11; JEM - 03/16/11; PPK - 03/28/11; MSSp- 05/23/11; WJK - 06/06/11 and 09/19/11 (two separate claims); BAE - 07/29/11, 08/19/11; DJS - 08/22/11; RM - 09/07/11; AJS - 09/07/11; RuL - 10/05/11; CHC - 11/09/11, 11/15/11; RH - 12/16/11; DJM - 01/04/12, 01/09/12; BM - 02/01/12; MEL - 03/02/12, 03/12/12; BDW - 03/28/12, 04/02/12; RGLe - 04/18/12; CWM - 04/18/12; KPK - 05/24/12, 05/25/12; EA - 06/29/12, 07/09/12; WA - 06/29/12, 07/09/12; DMS - 07/25/12, 08/06/12; JWB - 09/24/12, 10/3/12, 10/24/12; DL - 09/28/12; JS - 10/03/12; RL - 12/03/12, 12/17/12; MGH - 01/09/13; LL - 02/27/13; WGH - 03/18/13, 03/25/13, 04/02/13; NJM - 05/23/13; TB - 06/25/13; ALB - 08/28/13; CEB - 11/04/13; and WTE - 11/04/13, 11/06/13.

Patients seen by *Defendant Price* which were billed by Defendant Keystone under Defendant Fowler's NPI number include but are not limited to the following: LR - 05/16/11; WNM - 06/06/11; KM - 06/14/11; JW - 07/05/11; DD - 07/11/11; HF - 09/12/11; ESS - 11/01/11, 11/15/11; MM -11/15/11; RJR - 11/22/11; JMR - 11/29/11; VF - 12/19/11; SF - 12/20/11; TL - 12/20/11; AKT - 01/30/12; CS - 02/07/12; KY - 04/03/12, 04/10/12; DB - 04/23/12; RD - 05/28/12, 05/16/12, 05/30/12; RTh - 07/24/12, 08/02/12; DK - 09/04/12; BK - 10/16/12; HR - 11/21/12;

GWS - 12/17/12; DMM - 12/19/12, 12/26/12; JHM - 04/01/13; TM - 05/21/13, 05/24/13; BRS and two brothers - 05/21/13 and 09/03/14 (two separate claims); AAK - 07/08/13; MF - 01/28/14; TEM - 02/10/14; BR - 02/10/14; HFZ - 02/11/14; REF - 02/17/14; RLK - 03/03/14; DMJ - 03/03/14; JDP - 03/17/14; BJC - 06/02/14; JHM - 06/03/14; HK - 06/25/14; RJM - 07/22/14; EAC - 08/19/14; and GAC - 08/25/14.

When Relator took over the insurance billing from Defendant Keystone's employee Vivian Wenerick, she reviewed Ms. Wenerick's notes in Sycle. One note stated next to a FIP "MUST BILL UNDER TONY". When Relator was personally trained by Ms. Wenerick, Relator's notes indicate: "Provider: Anthony Fowler (always)."

Upon information and belief, Defendant Price knew or should have known that Defendant Keystone was billing her services under Defendant Fowler's NPI # number instead of her own.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the

submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

7. Billing For Unbundled Services That Were Already Billed For In A Bundled Price.

Federal Regulations prohibit unbundling for the sake of increasing reimbursement.

A patient's hearing aid service can be bundled into one CPT code (one price or amount to be billed to the insurance company). Services included in the bundled

price could include the hearing aid device, initial recommendation, fitting, verification, orientation, ongoing counseling, electroacoustic measures, repairs and modifications, reprogramming, and documentation, accessories, batteries, walk in office visits, auditory rehabilitation, warranties, and educational sessions.

An audiologist has the option of either bundling the services initially under one price or billing the FIP for each service under its own unique code.

'Unbundling' is defined as the breaking of a code into the sum of its parts to increase reimbursement. The best example is the unbundling of the vestibular code family. If you break it into pieces in an attempt to increase reimbursement, but do not document why you left out some of these other procedures, you could be unbundling. This could be flagged and considered a false claim. If you are going to only perform two to three of the four-bundle, you need to bill it out with the '-59' modifier, this way FIP knows this is distinct procedural services; documentation should support why you did not do all four pieces or why it was medically necessary to leave out a part of this testing.

Relator noticed on several occasions that there were so little notes in Defendant Fowler's patient's charts that she could not substantiate if all the procedures were done in either the bundled and / or unbundled package.

Defendant Keystone, by and though Defendant Fowler, would routinely instruct Relator to bill the FIP for hearing aid services at a bundled price but then also bill for the same services using un-bundled service codes.

If services were billed and not paid by FIP they were written off. Patients who did not have insurance coverage would only pay the "bundled" amount quoted for the hearing aids and were not charged for any additional services.

Patients were not offered a choice between a bundled price and an unbundled price; as should have been done. All hearing aid prices quoted to patients at Defendant Keystone were a bundled amount, which includes the services that were also billed.

On April 16, 2013, patient BMA purchased hearing aids from Defendant Fowler. He billed the FIP a bundled price of $4,700.00 (V5261) which included the hearing aid and the follow up services. The FIP paid Defendant $2,500 for this bundle. However a few weeks later on April 30, 2013, Defendant Fowler saw the patient for a follow up visit and billed the FIP $90.00 under CPT 92593 and the FIP paid Defendant Keystone $72.00 and on May 14, 2013 treated patient again for a follow up visit and billed the FIP $90.00 under CPT 92593 and the FIP paid Defendant Keystone $72.00, and again on June 4, 2013 treated this patient as a

follow up and billed the FIP $90.00 under CPT 92593 and the FIP paid Defendant Keystone $72.00.

On July 9, 2012, Patient EA was seen by Relator for a hearing aid services V5257 LT-RT. Defendant Keystone billed FIP the quoted bundled price of $4,200.00 and was paid $1000.00, then it unbundled the price and also billed for CPT 92595 electroacoustic evaluation for hearing aid for $60.00, CPT 92626 for evaluation of auditory rehabilitation status at $65.00 was paid $40.00, V5160 dispensing fee $450.00, and CPT 92593 hearing aid check for $40.00. On June 29, 2012 billed V5010 assessment for hearing aid at $90.00, and CPT 92591 hearing aid examination and selection at $90.00.

On July 9, 2012, Patient WA was seen by Relator for a hearing aid services V5257 LT-RT. Defendant Keystone billed FIP the quoted bundled price of $4,200.00 and was paid $1000.00, then it unbundled the price and also billed for CPT 92595 electroacoustic evaluation for hearing aid for $60.00, CPT 92626 for evaluation of auditory rehabilitation status at $65.00 was paid $40.00, V5160 dispensing fee $450.00, and CPT 92593 hearing aid check for $40.00. On June 29, 2012 billed V5010 assessment for hearing aid at $90.00, and CPT 92591 hearing aid examination and selection at $90.00.

Upon information and belief, Defendant Price knew or should have known that even though she quoted a bundled price to her patients, Defendant Keystone was billing the FIP the bundled and the unbundled price for the same services.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants'

fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

H. SLIDING SCALE PRICES

Audiologist Board of Ethics stated that it is a violation of ethics to provide professional courtesies or complimentary care for referrals or otherwise discounting care not based on documented need.

www.asha.org/Practices/ethics/Representation-of-Services/

A sliding fee scale may be used when the person served meets specific guidelines that are similarly available for all qualifies individuals within a practice. If a patient was below the poverty threshold Defendant Keystone was required to secure a statement to show that it gave this patient a waiver as to cost and/or co-pay.

Defendant Keystone by and through Defendant Fowler would discount product and service prices to patients if they were referred by another physician in the building.

Defendant Keystone had a "sliding scale" for hearing aid prices. Certain patients were given discounts varying between $200.00 to over $2000.00 at times, for no needed documented reason.

There was a set price for all hearing aids, which was required to be implemented by employees at Defendant Keystone, but this did not apply when

Defendant Fowler saw patients. Only when Defendant Keystone newspaper ads offered a $500.00 discount off of a set of aids, could Defendant Keystone employees discount them.

When the price was an issue for patients, other employees who sold hearing aids, were required to fit the patient with a lower level of technology/less expensive hearing aid, and could not offer these huge discounts. When patients were referred to Defendant Keystone, from a patient who was previously sold aids at a discounted price, then those patients would often be given the same discount, due to conflicts with "varied prices" quoted for the same product.

The following patients were given varied discounts from Defendant Fowler, without documented need including but not limited to the following: CFB - 04/07/11, $400.00 discount; RMB - 08/13/13, $600.00 discount; AJB - 08/10/11, $300.00 discount; EB - 01/31/12, $800.00 discount; MFB - 04/02/12, $600.00 discount; MC - 06/10/14, $700.00 discount; RC - 06/12/12, $400.00 discount; JD - 12/03/13, $1100.00 discount; HH - 10/16/12 or 10/17/12, $800.00 discount; BSH - 01/17/12, $300.00 discount; KMM - 02/02/12 or 02/15/12, $800.00 discount; DBM - 06/28/12, $300.00 discount; PWP - 12/07/11, $2800.00 discount; JR - 04/05/12, $600.00 discount; MSR - 09/19/12, $1200.00 discount; CDR - 09/25/13, $600.00 discount; KNS - 02/27/12, $300.00 discount; TBS - 04/03/14, $1200.00 discount; and JW - 06/28/12, $1200.00 discount.

Defendants Keystone and Fowler did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, said Defendants therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, said Defendants also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid said Defendants and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

I. WAIVING CO-PAYS

Because of the significant economic burden imposed on Government Programs, waiver of patient cost-sharing obligations has been prohibited. The Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), makes it illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid. When providers, practitioners, or suppliers routinely waive cost-sharing obligations for Government Program beneficiaries, they may be unlawfully inducing those beneficiaries to purchase their services. An exception exists that allows occasional waivers for patients in financial hardship; however, this exception is inapplicable to Defendant Keystone by and through Defendant Fowler's systematic and indiscriminate granting of waivers.

The Office of Inspector General, U.S. Department of Health & Human Services ("HHS-OIG") has long expressed concern that providers who routinely waive Medicare copayments or deductibles for reasons unrelated to individualized, good-faith assessments of financial hardship may be held liable under the Anti-Kickback Act. *See,* e.g., *Special Fraud Alert*, 59 Fed. Reg. § 65, 374 (Dec. 19, 1994). Such waivers may constitute prohibited remuneration to induce self-referrals as well as inducements to beneficiaries. OIG's guidance counsels against routine copayment waivers such as those employed by Defendant Keystone by and through Defendant Fowler.

2723 Defendant Keystone would routinely not charge the patient and write-off
2724 copays if the patient was favored, complained about the co-pay, or if it was a small
2725 amount such as Gateway FIP's copay was only $2.00; Defendant Fowler would fail
2726 instruct his staff to collect this copay.

2727 Defendant Keystone did not have a written policy in place that established
2728 guidelines for determining a patient's indigence.

2729 Upon information and belief, Defendant Price knew that the secretary was
2730 not always collecting the required co-pay on patients she provided service to.

2731 Defendants Keystone, Fowler and Price did act and/or conspired to
2732 intentionally and knowingly fail to meet the FIP conditions of participation and
2733 knowingly falsified or failed to supervise the falsification of the certification that
2734 they had met the conditions of participation (including each claim submitted), by
2735 knowingly submitting and causing the submission and/or failing to supervise the
2736 submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price
2737 therefore caused the submission of claims that were false and not eligible for
2738 reimbursement to FIP. By causing these claims that it knew were ineligible for
2739 reimbursement to be submitted to and paid for by FIP, Defendants Keystone,
2740 Fowler and Price also made, used, or caused to be made or used, false records or
2741 statements material to false or fraudulent claims. Had FIP known that these claims
2742 were only approved for coverage as a result of such false and fraudulent statements,

they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

J. DOUBLE BILLING

Diagnosis code 92557 is contained within V5010. V5010 is an audiogram as you would find for '57', but V5010 goes further to include additional measures that are necessary for the assessment of hearing aid selection. They are similar but not the same and they may not be billed on the same date of service because that would be double billing for the audiogram.

When 92557 and V5010 are billed on the same date, it is considered "double-billing", as code 92557 is contained in V5010. V5010 also includes MCL and UCL levels, which were not implemented to be done or documented on the audiogram. V5010 was billed based solely on known or anticipated payment from FIP; Defendant Keystone often billed the FIP 92557 and V5010 on the same date of service for a particular patient.

Audiologist professional services are included in the billing of the diagnostic test and should not be payed twice. The E/M office visit code was often billed by Defendant Keystone to the FIP in addition to codes for diagnostic tests that already encompassed the office visit code; therefore, it was considered double billing.

Examples of Defendant Keystone double billing the FIP for patient treatment are including but not limited to the following: BB- 08/10/11; EB - 01/31/12; JLB - 08/23/10; DEB - 04/06/10; VIC - 07/26/12; LVC - 05/24/11; WC - 09/20/10, 10/27/10; ENC - 02/15/11; MPD - 03/01/11; RD - 05/08/12, 05/16/12 (both dates on same claim); MMD - 10/16/13; HF - 04/15/10; BDF - 09/13/10; CG - 04/12/10; EFG - 03/23/11; RCJ - 02/03/11; DAJ - 02/15/11; KPK - 05/24/12; TCL - 06/15/10; DKL - 05/19/10; RGLa - 05/13/10; MM - 11/15/11; NEM - 08/19/10; KMM - 02/02/12; BR - 02/10/14; ALR - 05/27/10; MSR - 09/19/12; RJR - 11/22/11; CJS - 03/22/11; RDS - 01/17/12; FS - 07/31/12; AKT- 01/30/12; JW - 06/28/12; SDW - 03/21/11; and MLW- 05/27/10.

Upon info and belief, Defendant Price allowed the above codes to be fraudulently billed to the FIP.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that

they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

K. KICKBACKS / REBATES

Defendant Sonova directed Defendant Phonak in all its marketing and sales incentives to customers including Defendant Keystone.

Acceptance of gifts of any value by an audiologist from a company that manufacturers or supplies products that he professionally uses or recommends, may compromise, or give the appearance of compromising, the audiologist's ability to make ethical decisions, and should be avoided. A special problem is the Quid Pro Quo arrangement, which is receiving or accepting rewards in exchange for a purchase, referral, or recommendation of the product.

Under section 1128A(a)(5) of the Social Security Act (the Act), enacted as part of Health Insurance Portability and Accountability Act of 1996 (HIPAA), a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties (CMPs) of up to $10,000 for each wrongful act.

For purposes of section 1128A(a)(5) of the Act, the statute defines "remuneration" to include, without limitation, ... and transfers of items or services for free or for other than fair market value. (See section 1128A(i)(6) of the Act.) The statute and implementing regulations contain a limited number of exceptions.

(See section 1128A(i)(6) of the Act; 42 CFR 1003.101.) The Office of Inspector General (OIG) is responsible for enforcing section 1128A(a)(5) through administrative remedies.

> First, the OIG has interpreted the prohibition to permit Medicare or Medicaid providers to offer beneficiaries inexpensive gifts (other than cash or cash equivalents) or services without violating the statute. For enforcement purposes, inexpensive gifts or services are those that have a retail value of no more than $10 individually, and no more than $50 in the aggregate annually per patient. Second, providers may offer beneficiaries more expensive items or services that fit within one of the five statutory exceptions: waivers of cost-sharing amounts based on financial need; properly disclosed copayment differentials in health plans; incentives to promote the delivery of certain preventive care services; any practice permitted under the federal anti-kickback statute pursuant to 42 CFR § 1001.952; or waivers of hospital outpatient copayments in excess of the minimum copayment amounts.

There are ethical guidelines that are accepted by the Board of Directors of the Academy of Dispensing Audiologists and the American Academy of Audiologists. One such guideline is that any gifts accepted by the audiologist should primary benefit the patient should not be of substantial value. Gifts of minimal value ($100.00 or less) related to the audiologist's work (pens, earlights, notepads, etc.) are acceptable. Incentives or rewards based upon product purchases must not be accepted. This would include cash, gifts, merchandise, equipment or credit towards such items. No "strings" should be attached to any accepted gift. *Ethical Practice Guidelines on financial Incentives from Hearing Instrument Manufacturers,* American Academy of Audiology (1988).

49 Pa. Code § 45.102 (2)(f) *Principle of Ethics IV* provides: (2) Ethical proscriptions are as follows: (iii) A licensee may not use professional or commercial affiliations in a way that would mislead persons served or limit the services available to them.

49 Pa. Code§ 45.102 (2)(g) *Principle of Ethics V* provides: (1) A licensee shall maintain objectivity in all matters concerning the welfare of a person served. Accordingly, a licensee who dispenses products to a person served shall observe the following standards: (2) An ethical proscription is as follows: a licensee may not participate in activities that constitute conflicts of professional interest.

In or around , Defendant Keystone began selling Defendant Phonak hearing aids exclusively at all of its locations. By doing so, Defendant Keystone received from Defendants Sonova and Phonak, free product accessories and free hearing aids and as well huge discounts off its purchases of Phonak hearing aids.

Relator alleges that Defendant Keystone by and through Defendant Fowler sold Defendant Phonak products exclusively because Defendant Fowler was influenced by the incentive of cash savings.

The financial inducements paid by Defendant Phonak to Defendant Fowler and paid by Defendant Fowler to Defendant Price as described herein have caused said Defendants Fowler and Price certifications of FIP compliance to be false.

On March 1, 2006, Defendant Keystone offered Relator 8% commission on all hearing aid sales which increased to 10% in or about June 2006.

Relator expressed to Defendant Fowler several times that she felt uncomfortable only selling one brand of hearing aids to her patients. On April 10, 2014, Relator emailed Defendant Fowler and expressed concern stating "I wouldn't want any of them to think that was recommended for them was based on anything other than what would benefit them." Defendant Fowler told Relator "if patients ask for another brand try to talk them into Phonak".

Defendant Keystone also paid Defendant Price commission on hearing aids that she sold.

Defendants Keystone, Sonova, Phonak, Fowler, and Price were aware that compliance with the Anti-Kickback Statute and the Stark Law was a condition of payment by FIP.

Defendants Sonova and Phonak knowingly caused Defendant Keystone by and through Defendant Fowler to enter into arrangements that violated the Anti-Kickback Statute and the Stark Law.

Defendants Sonova and Phonak knew that Defendant Keystone by and through Defendants Fowler Price were making claims for payment to Medicare and other FIP in violation of the Anti-Kickback Statute and Stark Law.

2879 Notwithstanding the Anti-Kickback Statute and the Stark Law, it has been an
2880 integral part of Defendants Sonova and Phonak's illegal marketing strategy for
2881 them to induce Defendant Fowler to purchase hearing aids by regularly providing
2882 Defendant Keystone and Defendant Fowler with large numbers of free hearing aids
2883 and accessories in order to effectively lower the cost of the equipment.

2884 During the period of Relator's Complaint, each free hearing aid Defendant
2885 Keystone received from Defendant Phonak was generally worth between $2,000.00
2886 - $2,600.00; although Defendant Keystone would often bill the FIP a higher amount
2887 depending on known and/or anticipated reimbursement.

2888 Defendants Sonova and Phonak were aware that its kickbacks made to
2889 Defendants Keystone and Fowler were unlawful and for the purposes of carrying
2890 out their unlawful scheme (which caused false or fraudulent claims for payment for
2891 purchases of hearing aid and for medical care relating to the administration of the
2892 hearing aid to be presented to the federal government and caused the making or use
2893 of false records or statements material to those false or fraudulent claims).

2894 Said kickbacks caused Defendants Keystone, Fowler and Price to prescribe
2895 Defendants Sonova and Phonak hearing aids; Defendant Keystone's staff to fill out
2896 and submit prior authorization requests for Defendants Sonova and Phonak hearing
2897 aids; and caused patients to direct Defendant Keystone by and through Defendants

Fowler and Price to sell them Phonak hearing aids; as a result of this, claims for reimbursement were submitted to FIP.

Federal Insurance Programs do not cover claims for hearing aids and supporting services when there is a kickback involved in the underlying transaction — including claims that were submitted for payment of a hearing aid as a result of a kickback given to a health care professional to prescribe and/or sell that brand of hearing aid exclusively.

Claims submitted to FIP where a kickback is involved in the underlying transaction are false within the meaning of the Federal False Claims Act and State analogues.

In order to enroll in and bill Medicare, providers must sign CMS Form 855, which states:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. … I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

Claims that were submitted to FIP by Defendant Keystone as a result, in part or in whole, based on kickbacks provided by Defendants Sonova and Phonak were

2922 therefore false within the meaning of the Federal False Claims Act and State
2923 analogues.

2924 Defendants Sonova and Phonak kickbacks to Defendant Keystone caused the
2925 submission of claims that were false and not eligible for reimbursement to
2926 Government Programs.

2927 Defendants Sonova and Phonak offers of special pricing for unit
2928 commitments to Defendant Keystone were made knowingly and with the
2929 knowledge that this would cause the submission of false claims to Government
2930 Programs by Defendant Keystone.

2931 Government Programs paid Defendant Keystone reimbursements for those
2932 false claims, and as a result have incurred and continue to incur significant damages
2933 due to Defendants Sonova and Phonak illegal payment of kickbacks.

2934 By causing these claims that it knew were ineligible for reimbursement to be
2935 submitted to and paid for by Government Programs, Defendants also made, used, or
2936 caused to be made or used, false records or statements material to false or
2937 fraudulent claims, as described above.

2938 By giving illegal kickbacks, Defendants Sonova and Phonak causes and/or
2939 induced Defendant Keystone who sought reimbursement for hearing aids from
2940 federal government-funded health insurance and assistance programs to file false
2941 and/or fraudulent certifications, either express or implied regarding compliance

with the Anti-Kickback Act of 1986, 41 U.S.C. §§ 51 et seq., the Medicare/Medicaid Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7a & 7b(b) and the Stark Law, 42 U.S.C. § 1395NN.

As of the year 2014, the Affordable Care Act requires device companies to publically report nearly all gifts or payments they make to physicians beginning in 2013. The Social Security Act requires CMS to collect information from applicable manufacturers and group purchasing organizations (GPOs) in order to report information about their financial relationships with physicians and hospitals. 'Open Payments' is the federally run program that collects the information about these financial relationships and makes it available to you.

Upon information and belief, Defendant Phonak has not registered its free products or discounts that it gives to Defendant Keystone.

Upon information and belief, Defendant Price sold her patients hearing aids and accessories that were provided to Defendant Keystone through a fraudulent kickback scheme.

All the Defendants knowingly and repeatedly made statement in order to receive money from the Federal Government, the statements were false, Defendants knew they were false, Defendant Keystone received reimbursement from FIP for these false statements, and Defendant Keystone paid Defendants Fowler and Price and did not return the money to the Federal Insurance Program.

L. DISREGARDED SAFETY AND HYGIENIC PROTOCOL

49 Pa. Code § 45.103 provides the following: As used in section 10(5) of the act (63 P. S. § 1710(5)), the term ''unprofessional conduct'' includes, but is not limited to, the following types of conduct:

> (5) Committing an act of gross negligence, gross malpractice or gross incompetence, or repeated acts of negligence, malpractice or incompetence. ... (9) Committing an act involving moral turpitude, dishonesty or corruption when the act directly or indirectly affects the health, welfare or safety of citizens of this Commonwealth. If the act constitutes a crime, conviction in a criminal proceeding is not a condition precedent to disciplinary action by the Board.

Defendant Keystone by and through Defendant Fowler would deliberately disregard safety and hygienic protocol for patients being tested. Defendant Fowler would repeatedly use the suctioning machine without disinfecting and/or sterilizing the machine's tips, he would fail to change the otoscope tip between patients use, fail to wipe down counters, fail to wash his hands between patients, and failed to disinfect the headphones used for testing.

Because of Defendant Fowler's inaction he committed gross incompetence and/or negligence and/or malpractice all of which would have made him ineligible to perform these tests on patients therefore he would not have been eligible to submit through Defendant Keystone insurance claims for reimbursement for this test from the Federal Government.

Defendants Keystone and Fowler did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and/or healthcare rules and regulations and did knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, said Defendants therefore caused the submission of claims that were false and not eligible for reimbursement from Government Healthcare Programs. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, said Defendants also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, and it did not reimburse the FIP for these illegal payments. Because FIP paid reimbursements for the resulting false claims, they incurred and continue to incur significant damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

M. FAILED TO SECURE BUSINESS ASSOCIATE CONTRACTS

3001 HIPAA requires that an audiologist practice that has an association with an
3002 outside vendor, that may have access to patient names, have a signed Business
3003 Associate Contract in place.

3004 Defendant Keystone failed to have Defendants Phonak and/or Sonova sign a
3005 Business Associates Contract.

3006 Upon information and belief, Defendant Keystone failed to have any of its
3007 outside vendors, including but not limited to, an ear-mold lab and/or a hearing aid
3008 lab, sign a Business Associate Contract.

3009 Defendant Keystone contracted with 'The Green Clean' that would clean
3010 Defendant Keystone's Hanover office; upon information and belief, Defendant
3011 Keystone failed to have 'The Green Clean' sign a Business Associate Contract.

3012 Defendants Keystone and Fowler did act and/or conspired to intentionally
3013 and knowingly fail to meet the FIP conditions of participation and/or healthcare
3014 rules and regulations and did knowingly falsified or failed to supervise the
3015 falsification of the certification that they had met the conditions of participation
3016 (including each claim submitted), by knowingly submitting and causing the
3017 submission and/or failing to supervise the submission of false and fraudulent
3018 claims, said Defendants therefore caused the submission of claims that were false

and not eligible for reimbursement from Government Healthcare Programs. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, said Defendants also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, and it did not reimburse the FIP for these illegal payments. Because FIP paid reimbursements for the resulting false claims, they incurred and continue to incur significant damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

N. FAILED TO RETURN MONEY TO FEDERAL INSURANCE PROGRAMS

Audiologists are aware of the changes as a result of the Affordable Care Act (ACA) of 2010, also known as the health care reform bill. Overpayments must be returned to the Medicare contractor or Medicaid agency within 60 days after discovery, or the claim will be considered a False Claim and stiff penalties will apply.

Defendant Keystone was required to reimburse the FIP for payment when hearing aids were returned to its office for credit; however, if the insurance had paid

for fitting or dispensing, then that amount was not refunded, only whatever was paid towards the hearing aids (the insurance companies weren't aware that the aid cost billed was a "bundled" amount that normally included fitting and dispensing).

Defendant Keystone never repaid the FIP for payments it received from submitting to the FIP numerous and varied fraudulent claims that are listed throughout this Complaint.

Upon information and belief, Defendant Price never reimbursed the FIP for payments that Defendant Keystone received from the FIP on claims for services that she provided and knew were fraudulently billed to the FIP.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims

were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

O. TERMINATION

Defendant has a duty under the False Claims Act, 31 U.S.C. § 3730(h), to refrain from taking retaliatory actions against employees who take lawful actions in furtherance of a False Claims Act action, including investigation for, testimony for, or assistance in an FCA action.

Relator took lawful actions in furtherance of a False Claims Act action, and other related laws including but not limited to investigation for, testimony for, or assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws. In or around June 2014, Relator started to submit complaints, on the actions listed throughout this Complaint, with several Pennsylvania State Government Agencies; which Defendants Keystone and Fowler discovered and acted upon.

In or about September 2014, Defendant terminated Relator's employment.

Relator was discriminated against in the terms and conditions of his employment by Defendant, by and through its officers, agents, and employees because of lawful acts done by her in the furtherance of an action under the False Claims Act.

The actions of Defendant damaged and will continue to damage Relator in violation of 31 U.S.C. § 3730(h), in an amount to be determined at trial.

Pursuant to 31 U.S.C. § 3730(h), Relator is entitled to litigation costs and reasonable attorneys' fees incurred in the vindication of her reputation and the pursuit of her retaliation claims.

Throughout Relator's employment with Defendant Keystone, she constantly expressed her concern to her boss Defendant Fowler about all the above mentioned violations. He always acted like he did not care that violations were occurring and stated: "If he was caught he would just pay the fine."

On April 10, 2014, Relator emailed Defendant Fowler and once again expressed her concern and displeasure on how he expected her to bill insurances and enter codes depending on which insurance paid what amount for the service. Excerpts are as follows

- "I just want to be able to enjoy those busy days without the added stress of anything related to billing whatsoever."
- "… but I feel it wouldn't have to be so stressful if things were just done properly/correctly, instead of just putting in services, not knowing what will be denied and why its denied. I feel like you don't even care whether or not is done right, that if you get paid ok, and if billed incorrectly or denied for a certain reason, then fine. You don't seem to be concerned with billing correctly or for someone to take the time to know the ins and outs of billing to achieve a better payment for the services that YOU provide."
- "…I didn't offer to help with billing so that it would be an endless game of wondering who pays what …"
- "I feel like you rush through things when you are billing … double bill codes and don't remember to check dates …"
- "You know we should have some kind of disinfectant/infection control process implemented, don't you? … Yes, I am a germ freak, so it grosses me out knowing that nothing is ever wiped down each day….I don't know how you do it."

- "…when I see a patient that is normally your patient, and there are no notes whatsoever as to what issues they've been having , what adjustments you've made, nothing in notes …..it drives me crazy"
- "Ok …so it's nice that you can discount aids patients, but do you realize just how often you do it? Do you know what you've discounted already this year? OMG ….. it's close to $10,000!!!!"

Defendant Fowler replied to Relator by email on April 10, 2014 excerpts are as follows:

- "Basically you've presented a very strong argument, yourself, for why you should not be working for me."
- "All factors mentioned in your message have been present for many years…"
- "The fact is I'm very familiar with what an Audiologist is allowed to bill for, legally."
- "You kind of answered the cleaning issue yourself with your statement about "germ freak". It's your hang up and shouldn't impact me."
- "The fact that you took the day off today and spent the time looking up how much I discounted hearing aids is mind-boggling. This is none of your business. You've also spent time looking at what we've grossed

over certain periods of time. ...when situations have arisen where a patient comes and there is a dilemma caused by this ... we've moved through it fine. Once again, a situation that causes you stress, but no one else. And it was all caused by you looking into things that are none of your business."

- "... I will not be making any significant changes in the business. ...I don't answer to anyone with regard to the business,,, that's why I started it. "

Relator sent a reply email to Defendant Fowlers email later that night stating the following: "And if you're familiar with what is allowed to be billed, then I won't question/comment on anything different. I was again suggesting to know the "ins and outs" of billing, in case we ever get audited, which would affect all our jobs, if there's a lot of things not being done correctly."

Defendant Fowler replied by email stating the following: "Audits...the sure-fire way to get audited is to bill unusual services and use modifiers in audiology."

In or around September 2014, Defendant Fowler hired someone new to assume the duties of entering information into Sycle and to bill through Emdeon to the FIP.

Defendant Fowler asked Relator to train this new hire on how to enter information into the system and how to bill the FIP. Relator refused stating she did not think the current billing procedures were correct and did not want to train the new hire on false procedures.

Although Relator refused to train the new hire on billing procedures, Defendant Fowler scheduled the training to proceed. Relator felt forced to take a sick day.

On or about September 24, 2014, Relator was terminated by Defendant Fowler from her position with Defendant Keystone.

VII. CAUSES OF ACTIONS

COUNT ONE - 31 U.S.C. § 3729(a)(1)
Violations of Federal False Claims Act - Presentation of False Claim
(1) Defendant submitted a claim to the Government;
(2) claim was false; and (3) the Defendant "knew" the claim was false

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

This is a claim for triple damages, civil penalties, cost and attorney fees and other damages and costs this Court deems proper under the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq. as amended. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to the United States

Government Insurance Programs false or fraudulent claims for the payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States of medical services and equipment.

United States, unaware of the falsity of the claims and/or statements caused to be made by Defendants and in reliance on the accuracy thereof, paid said Defendant Keystone for claims that would otherwise not have been allowed.

The amounts of the false or fraudulent claims caused by the Defendants to be submitted to the United States were material. By reason of Defendants wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally.

COUNT TWO - Act, 31 U.S.C. § 3729(A)(1)(G)

Reverse False Claims
(False Record to Avoid an Obligation to Refund)

Relator re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs of this Complaint.

This is a claim for damages and costs the Court deems proper, triple damages, civil penalties, cost and attorney fees under the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq. as amended.

Defendants knowingly caused to be made or used false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States and knowingly concealed and improperly avoided or decreased an obligation to pay or transmit money or property to the Government. By virtue of the false records or false statements caused to be made by Defendants, the United States paid Defendant Keystone. Defendant Keystone failed to reimburse the Federal Government for these payments and caused the Federal Health Care Programs to suffer material damages.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally.

<u>COUNT THREE</u> - 31 U.S.C. § 3729(a)(2)
Violations of Federal False Claims Act – Making or Using False Record or Statement
(1) Defendant created a record and used the record to get the Government to pay its claim; (2) record was false; and (3) Defendant "knew" the record was false

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

This is a claim for damages the Court deems proper, triple damages, civil penalties, cost and attorney fees under the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq. as amended.

By virtue of the acts described above, Defendants knowingly made or caused to be made or used false records or statements to get false or fraudulent claims for payment or approval by the United States Government Insurance Programs and continues to make, use or cause false records and statements to be made or used to get false or fraudulent claims for Defendant Keystone to be paid or approved by the United States.

Plaintiff United States, unaware of the falsity of the records and/or statements caused to be made and used by Defendant Keystone and in reliance on the accuracy thereof, paid and approved and continues to pay and approve, Defendant Keystone for claims that were ineligible for reimbursement and would not have been paid or approved if any part of the truth were known.

The amount of the false or fraudulent claims caused by the Defendants to be submitted to the United States were material. By reason of Defendants wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally.

COUNT FOUR - 31 U.S.C. § 3729(a)(3)

Violations of Federal False Claims Act – Conspiracy

(1) The Defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States, and (2) One or more conspirators performed any act to affect the object of the conspiracy.

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

This is a claim for damages the Court deems proper, triple damages, civil penalties, cost and attorney fees under the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq. as amended.

Defendants entered into conspiracies between each other for the purpose of defrauding the United States.

By the foregoing acts and omissions, Defendants took actions in furtherance of its conspiracies, including but not limited to the discount and/or free price of its hearing aids to its co-conspirators Defendants Keystone and Fowler, in exchange for being the exclusive seller of hearing aids in any of the Defendant Keystone office locations; thereby, increasing the number of Defendant Phonak hearing aids submitted to the United States for payment.

By the foregoing acts and omissions, Defendants entered into these unlawful marketing conspiracies to defraud the United States by causing false and fraudulent claims to be paid and approved in violation of the False Claims Act.

At all times relevant to this Complaint, Defendants acted with the requisite knowledge.

By virtue of the acts described above, Defendants knowingly engaged in kickback schemes for the purpose of inducing, and did induce, the presentation of false or fraudulent claims to the United States Government for the payment of medical services as described above.

As detailed above, Defendants knowingly conspired and may still be conspiring to commit acts in violations of these laws. Defendants committed overt acts in furtherance of the conspiracy as described above.

The United States, unaware of the conspiracy, statements or claims made by the defendants or the kickbacks involved, paid Defendant Keystone for claims that would otherwise not have been allowed.

WHEREFORE, as a direct and proximate consequence of Defendants conspiratorial conduct, the United States has suffered substantial losses in an amount to be proved at trial. Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally.

COUNT FIVE - 41 U.S.C. §§ 52-53
Violations of Anti-Kickback Act

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

As a direct and proximate consequence of Defendants conduct, the United States has suffered substantial losses in an amount to be proved at trial and Plaintiffs are entitled to damages, fines, costs attorney fees and other damages and costs the Court deems proper.

By engaging in the conduct described in the foregoing paragraphs, Defendants violated the Anti-Kickback Act.

Defendants knowingly caused Defendant Keystone to present claims to the United States government and to Federal Insurance Programs that were the product of the payment of the above described kickbacks. The payment of a kickback to induce a prescription for a hearing aid constitutes a "thing of value … for the purpose of improperly obtaining or rewarding favorable treatment;" which was designed to and in fact did increase level of business in violation of the Anti-kickback Act.

Defendants did not report these free products and/or discounts to Medicare, Medicaid and other government funded programs. Thus Defendant facilitated and caused Defendant Keystone by and through Defendants Fowler to falsely certify, either expressly or impliedly, that it had complied with the aforesaid laws and was

qualified to participate in the FIP and, in particular, qualified to receive reimbursements thereunder.

As a result of the conduct set forth in this cause of action, the Federal Government suffered harm as a result of paying and reimbursing for hearing aids which, had the government known such hearing aids were prescribed as a result of a kickback, the Government would not otherwise have paid for and /or reimbursed.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally.

COUNT SIX - 42 U.S.C. §§ 1320a-7a
Violations of the Anti-Kickback Statute

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

As a direct and proximate consequence of Defendants' conduct, the United States has suffered substantial losses in an amount to be proved at trial and Plaintiffs are entitled to damages, fines, costs attorney fees and other damages and costs the Court deems proper and Defendants should be fined up to $50,000 per kickback violation, imprisonment of up to five (5) years, or both; exclusion of the provider from participation in Federal Health care programs; and other damages and/or costs as the court deems.

By engaging in the conduct described in the foregoing paragraphs, Defendants violated the Anti-Kickback Statute.

Defendants knowingly caused Defendant Keystone to present claims to the United States government and to Federal Insurance Programs that were the product of the payment of the above described kickbacks; which constitute remuneration to increase the level of business in violation of said Statute.

Defendants did not report these free products and/or discounts to Medicare, Medicaid and other government funded programs. Thus Defendants facilitated and caused Defendant Keystone by and through Defendants Fowler and Price to falsely certify, either expressly or impliedly, that it had complied with the aforesaid laws and was qualified to participate in the Government Insurance Programs and, in particular, qualified to receive reimbursements thereunder.

As a result of the conduct set forth in this cause of action, the Federal Government suffered harm as a result of paying and reimbursing for hearing aids which, had the Federal Government known such hearing aids were prescribed as a result of a kickback, the Federal Government would not otherwise have paid for and /or reimbursed.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally.

COUNT SEVEN
42 U.S.C. § 1395nn and further implemented at 42 C.F.R. §§ 411.350 et seq.
Violation of the Stark Law

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

Defendants Sonova and Phonak had compensation arrangement with Defendant Fowler and knowingly caused Defendant Fowler and Defendant Price to refer Defendants Sonova and Phonak hearing aids for which payment otherwise may be made in violation of the Stark Law and for which Defendants are liable for a penalty of $15,000 for each such claim.

Defendants Sonova and Phonak knowingly entered into improper arrangements or schemes with Defendants Fowler and for which Defendants are liable for a civil penalty of $100,000 for each such arrangement or scheme.

Defendant Keystone did not report these free products and/or discounts to Medicare, Medicaid and other FIP. Thus Defendants Sonova and Phonak facilitated and caused Defendant Keystone by and through Defendants Fowler and Price to falsely certify, either expressly or impliedly, that it had complied with the aforesaid laws and was qualified to participate in the Government Insurance Programs and, in particular, qualified to receive reimbursements thereunder.

As a result of the conduct set forth in this cause of action, the Federal Government suffered harm as a result of paying and reimbursing for hearing aids

which, had the Government known such hearing aids were prescribed as a result of a kickback, the Government would not otherwise have paid for and /or reimbursed.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally for all damages and costs the Court deems proper, to deny payment for the designated health services, refund of amounts collected from improperly submitted claims, and a civil monetary penalty of up to $15,000 for each improper claim submitted. Physicians who violate the statute may also be subject to additional fines per prohibited referral. In addition, providers that enter into an arrangement that they know or should know circumvents the referral restriction law may be subject to a civil monetary penalty of up to $100,000 per arrangement.

COUNT EIGHT - 42 U.S.C. § 1320a-7a
Civil Monetary Penalties Law

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

For all of the Defendants' actions listed throughout this Complaint, said Defendants did violate this Law.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and

against each Defendant jointly and severally a penalty of $10,000 - $50,000.00 per violation and up to three times the amount unlawfully claimed, exclusion from participation in Federal health care programs; and award Plaintiffs other damages and costs it deems proper.

COUNT NINE - 62 P.S. § 1401 et seq.
Pennsylvania Fraud and Abuse Control Act

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

For all of the Defendants' actions listed throughout this Complaint, Defendants did violate this Act.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally to pay a maximum penalty of $25,000 and up to 10 years' imprisonment, be required to repay the excess benefits or payments they received plus interest, preclusion of a provider from participating in the medical assistance program for a period of five (5) years from the date of conviction plus award Plaintiffs other damages and costs it deems proper.

COUNT TEN - 18 U.S.C. § 287
Criminal False Claims Act,

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

Whoever makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, "fined not more than $10,000 or imprisoned not more than five years, or both".

Although this is a criminal statue, Relator is entitled to a percentage of the monetary recovery through fines etc., under the Alternative Remedies provision of the FCA.

WHEREFORE, Relator on behalf of herself and on behalf of the United States of America demands and prays that judgment be entered in its favor and against each Defendant jointly and severally.

COUNT ELEVEN - 31 U.S.C. § 3730(h)
FCA Wrongful Discharge

Relator re-alleges and incorporates by reference the allegations contained in all of the foregoing paragraphs as if fully set forth herein.

Relator was terminated from her employment with Defendant Keystone because of her lawful acts of initiating, investigating, and reporting the misconduct of the Defendants to employees of the State Regulatory Agency.

Relator was discriminated against in the terms and conditions of her employment by Defendants Keystone and Fowler, by and through its officers, agents, and employees because of lawful acts done by him in the furtherance of an action under the False Claims Act.

The actions of Defendant damaged and will continue to damage Relator in violation of the FCA; 31 U.S.C. § 3730(h)

WHEREFORE, Relator demands and prays that judgment be entered in its favor and against Defendants Keystone and Fowler jointly and severally to pay Relator two times the amount of her back pay and benefits, plus interest on the back pay and benefits from the date of discharge to the date of reinstatement; interest, compensation for special damages, punitive damages including litigation cost, and reasonable attorney fees, and other damages and costs this Court deems proper pursuant to 31 USC §3730(h) .

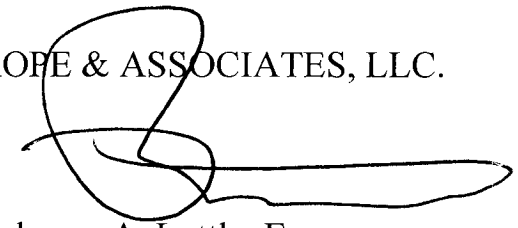
VIII. REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury.

Dated this 28th day of August 2015.

Sincerely,

KOPE & ASSOCIATES, LLC.



Rebecca A. Lyttle, Esq.
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717-761-7573
(F) 717-761-7572
rlyttle@kopelaw.com
Counsel for the Relator

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing Complaint was served by Federal Express, this 28th day of August, 2015, to:

Attorney General of the United States
False Claims Act Division
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-001

I HEREBY CERTIFY that a copy of the foregoing Complaint was served by Hand Delivery, this 28th day of August, 2015, to:

United States Attorney's Office for the Middle District of Pennsylvania
The Civil False Claims Act Division
Harrisburg Federal Building and Courthouse
228 Walnut Street, Suite 220
P.O. Box 11754
Harrisburg, PA 17108-1754

Sincerely,

KOPE & ASSOCIATES, LLC.

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Counsel for the Relator